HFI-35 (Purged)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 11 2001

WARNING LETTER

Ref:OC:I1-1886

via FEDERAL EXPRESS

John Leferman
Managing Director
KLS Electronics
27599 Schoolcraft Rd.
Livonia, Michigan 48150-2217

Dear Mr. Leferman:

This letter is written to advise you of items of noncompliance with the Federal laser product performance standard (21 CFR 1040.10) and radiological health regulations. These items were encountered during a Food and Drug Administration (FDA) inspection of a KLS Electronics laser light show at the IDI Convention in Las Vegas, Nevada by Gary L. Zaharek, Pacific Region Electro-Optics Specialist, on October 20, 2000.

1. 21 CFR 1040.11(c) requires that all demonstration laser products comply with applicable portions of 21 CFR 1040.10 for Class I, IIa, II, or IIIa laser products. An approved variance from 21 CFR 1040.11(c) is required for Class IIIb and IV demonstration laser products, including laser projectors and laser light shows.

   It was noted during the inspection that you were operating an uncertified laser projector and performing a laser light show without an approved variance from FDA. Prior to using laser projectors to perform a laser light show in the United States you are required to submit the following to the FDA:
   (a) a Product Report describing how the laser projector is in compliance with 21 CFR 1040.10,
   (b) a Laser Light Show Report describing the laser light show, and
   (c) an application for a variance from 21 CFR 1040.11(c) describing what alternative means of radiation safety and protection will be provided.

2. 21 CFR 1010 requires that all electronic products be certified as compliant with the Federal performance standards. The manufacturer must certify compliance with applicable standards based on a testing program to ensure radiation safety. Certification is indicated by a certification label that is permanently affixed to the laser product. Laser projectors used in laser light shows must specifically comply with 21 CFR 1040.10 and 1040.11 except where deviations are allowed by the conditions specified in an approved variance from the FDA.

It was observed during the inspection that your laser projector was not certified as compliant with applicable standards (21 CFR 1010, 21 CFR 1040), and was missing the following required labeling:
(a) certification label required by 21 CFR 1010.2,
(b) identification label required by 21 CFR 1010.3,
(c) warning logotype label required by 21 CFR 1040.10(g)(1) through 1040.10(g)(4)
(d) aperture label(s) required by 21 CFR 1040.10(g)(5), and
(e) protective housing label(s) required by 21 CFR 1040.10(g)(6) and 1040.10(g)(7).

The following failures to comply with the regulations covering records and reports were observed:

1. 21 CFR 1002.10 requires that manufacturers of laser products and laser light shows submit reports to demonstrate that their equipment and shows are in compliance with the Federal laser product performance standard.

   It was observed during the inspection that you were using a laser projector for which no product report had been submitted to FDA. It is also noted that no laser light show reports have been submitted to FDA. You are required to submit product reports for the laser projector and laser light show, in addition to an application for a laser light show variance, prior to performing laser light shows.

2. 21 CFR 1002.30 requires that all laser product manufacturers maintain records of quality control procedures, results of radiation safety testing, radiation safety communication, and production and distribution records.

   It was observed during the inspection that no laser light show testing or setup records were maintained. You are required to maintain testing records of testing and setup conducted for each laser light show performance.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. The production or performance of a laser light show is considered to be an act of manufacturing. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000 without further notification by the FDA.

You are not being requested to submit a formal corrective action plan at this time, however, all of your equipment and future performances must comply with the Federal performance standard/variance. As such, you may not conduct additional laser light shows until the required documentation is submitted to FDA and you are granted a variance to perform laser light shows. Persons failing to correct violations may be subject to regulatory action. If you feel that the alleged failures to comply do not exist, you may present your views and evidence within 15 days of receipt of this letter.

You must respond to each of the items listed above stating what actions you will take and what changes you will make to your equipment or shows to achieve full compliance. Your response should be submitted within 14 days of receipt of this letter, and should describe what laser light shows you have produced or performed and to specify whether they and/or the projection equipment used for them were certified. Your response should clearly indicate the reference number found at the top of this letter.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a **copy** of your response to: Director, Compliance Branch, San Francisco District Office, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have further questions regarding these requirements, please contact LT Sean Boyd of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Gladys Rodriguez for

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Drafted:SMBoyd:smb:01/09/01
Reviewed:LDSmith:
Reviewed:CLFigueroa:
Final:smb:

SMB 1/9/2001
CLF 1/11/2001
LDS 1/10/2001
SMB 1/11/01

File: L1/ KLS Electronics (no code available yet) (Yellow)

Ref: OC track 85702

cc: SMBoyd
EPB Board
Zaharek (HFR-PA1530)
SAN-DO (HFR-PA100)
SAN-DO Compliance Branch (HFR-PA140)
RRHR-PA (HFR-PA19)
DE3 Chron File
DE3 Firm File
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HFZ-325
HFA-224
HFC-135
HFC-210
HFZ-305 (purged)
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